

# WHO Surgical Site Infection Prevention Guidelines

## Web Appendix 17

### Summary of a systematic review on drapes and gowns

#### 1. Introduction

Sterile surgical drapes are used during surgery to prevent contact with unprepared surfaces and to maintain the sterility of environmental surfaces, equipment and the patient's surroundings. Similarly, sterile surgical gowns are worn over the scrub suit of the operating team during surgical procedures to maintain a sterile surgical field and reduce the risk of transmission of pathogens to both patients and staff.

Surgical gowns and drapes are fabricated from either multiple- or single-use materials. There is considerable variation in design and performance characteristics within each of these two broad categories, which reflects the necessary trade-offs in economy, comfort and degree of protection required for particular surgical procedures<sup>1</sup>.

During surgical procedures, the risk of pathogen transmission increases if the barrier materials become wet. Consequently, the multiple- or single-use materials of the drapes and gowns used in a surgical procedure should prevent the penetration of liquids. Reusable materials are typically composed of different tightly-woven textiles and/or knitted cotton, or other fabrics possibly blended with polyester and/or chemically treated. These products have to be durable and provide protection after many cycles of processing and treatment. Disposable surgical drapes and gowns are typically composed of non-woven materials of synthetic and/or natural origin, possibly combined with chemical treatment<sup>2</sup>.

Adhesive plastic incise drapes, plain or impregnated with an antimicrobial agent (mostly an iodophor), are used on the patient's skin after the completion of surgical site preparation. The film adheres to the skin and the surgeon cuts through the skin and the drape itself<sup>3</sup>. Such a drape is theoretically believed to represent a mechanical and/or microbial barrier to prevent the migration of microorganisms from the skin to the operative site<sup>4</sup>. However, some reports showed an increased recolonization of the skin following antiseptic preparation underneath adhesive drapes compared to the use of no drapes<sup>5</sup>.

A Cochrane review<sup>6</sup> and its updates<sup>3,7</sup> on the effect of adhesive incise drapes for the prevention of surgical site infection (SSI) found that there is no evidence that plastic adhesive drapes reduce SSI. No recommendation is available on the use of disposable or reusable drapes and gowns. The guidelines of the Society for Healthcare Epidemiology of America (SHEA)/Infectious Diseases Society of America (IDSA) issued in 2014 recommend that plastic adhesive drapes with or without antimicrobial properties should not be used routinely as a strategy to prevent SSI<sup>8</sup>. Nevertheless, the United Kingdom (UK) National Institute for Health and Care Excellence (NICE) issued a guideline in 2008, which recommends that an iodophor-impregnated drape should be used if a plastic adhesive drape is required<sup>9</sup>.

## 2. PICO questions

1. Is there a difference in SSI rates depending on the use of disposable non-woven drapes and gowns vs. reusable woven drapes and gowns?

1.1 Is there a difference in SSI rates depending on whether disposable non-woven or reusable woven **drapes** are used?

1.2 Is there a difference in SSI rates depending on whether disposable non-woven or reusable woven **gowns** are used?

Population: patients of any age undergoing inpatient or outpatient surgical procedures

Intervention: disposable non-woven drapes and surgical gowns

Comparator: reusable woven drapes and surgical gowns

Outcomes: SSI, SSI-attributable mortality

2. Does changing drapes during operations affect the risk of SSI?

Population: patients of any age undergoing inpatient or outpatient surgical procedures

Intervention: scheduled change of drapes during operations

Comparator: use of one set of drapes or a change, depending on specific situations (for example, massive blood loss)

Outcomes: SSI, SSI-attributable mortality

3. Does the use of disposable adhesive incise drapes reduce the risk of SSI?

Population: patients of any age undergoing inpatient or outpatient surgical procedures

Intervention: plastic adhesive incise drapes

Comparator: no adhesive incise drapes

Outcomes: SSI, SSI-attributable mortality

## 3. Methods

The following databases were searched: Medline (PubMed); Excerpta Medica database (EMBASE); Cumulative Index to Nursing and Allied Health Literature (CINAHL); Cochrane Central Register of Controlled Trials (CENTRAL); and the WHO Global Health Library. The time limit for the review was between 1 January 1990 and 31 December 2014; no language restriction was applied. A comprehensive list of search terms was used, including Medical Subject Headings (MeSH) (Appendix 1).

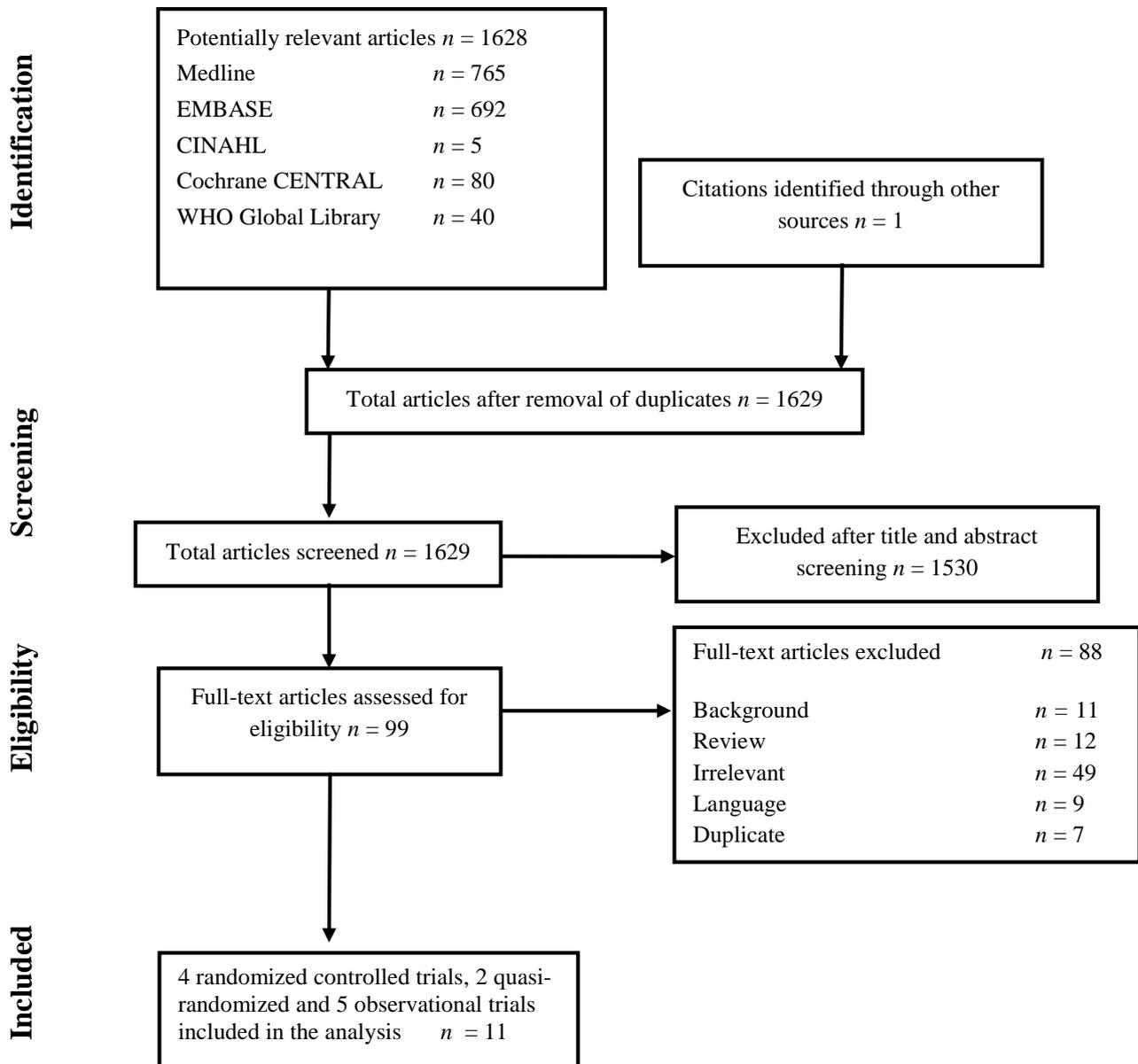
Two independent reviewers screened titles and abstracts of retrieved references for potentially relevant studies. The full text of all potentially eligible articles was

obtained. Two authors independently reviewed the full text articles for eligibility based on inclusion criteria. Duplicate studies were excluded. Two authors extracted data in a predefined evidence table (Appendix 2) and critically appraised the retrieved studies. Quality was assessed using the Cochrane Collaboration tool to assess the risk of bias of randomized controlled studies (RCTs) <sup>10</sup> (Appendix 3a) and the Newcastle-Ottawa Quality Assessment Scale for cohort studies (Appendix 3b) <sup>11</sup>. Any disagreements were resolved through discussion or after consultation with the senior author, when necessary.

Meta-analyses of available comparisons were performed using Review Manager v5.3 as appropriate <sup>12</sup> (Appendix 4). Adjusted odds ratios (OR) with 95% confidence intervals (CI) were extracted and pooled for each comparison with a random effects model. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology <sup>13</sup> (GRADE Pro software) was used to assess the quality of the body of retrieved evidence (Appendix 5).

#### 4. Study selection

Flow chart of the study selection process



## 5. Summary of the findings and quality of the evidence

Eleven studies<sup>14-24</sup> (4 randomized controlled trials [RCTs]<sup>14,20,23,24</sup>, 2 quasi-RCTs<sup>15,19</sup> and 5 observational studies<sup>16-18,21,22</sup>) comparing overall the use of disposable non-woven drapes and gowns vs. reusable woven drapes and gowns were identified with SSI as the primary outcome.

### Findings related to **PICO question 1**

Five studies (one RCT<sup>14</sup>, one quasi-RCT<sup>15</sup> and 3 observational studies<sup>16-18</sup>) compared disposable non-woven **drapes and gowns** vs. reusable woven **drapes and gowns** and disposable non-woven **drapes** vs. reusable, woven **drapes** (Appendix 2). The literature search did not identify any studies focusing on gowns only (comparing disposable non-woven gowns with reusable woven gowns).

After careful appraisal of the studies, the following *two comparisons* were performed:

1.1 Disposable non-woven **drapes and gowns** vs. reusable woven **drapes and gowns**.

1.2 Disposable non-woven **drapes** vs. reusable woven **drapes**.

### *Results according to the comparisons*

1.1 Four studies (one RCT<sup>14</sup>, one quasi-RCT<sup>15</sup>, and 2 observational studies<sup>16,18</sup>) compared the use of disposable non-woven drapes and gowns vs. reusable woven drapes and gowns to decrease the risk of SSI. These studies included clean and clean-contaminated general surgery, orthopaedic, neurosurgery, plastic cardiothoracic and coronary artery surgical procedures. Types and materials of disposable and reusable drapes and gowns differed between studies (Appendix 2).

The effect of the intervention varied among the studies. One study<sup>15</sup> reported that the use of disposable non-woven drapes may be beneficial for the reduction of SSI, but the effect estimate was not statistically significant. Two studies<sup>14,18</sup> estimated that there was no difference between the intervention and the control group, and one study<sup>16</sup> showed that using the intervention may have some harm, but this was not statistically different from the control group.

Meta-analysis of the RCT and the quasi-RCT showed that the use of disposable non-woven drapes and gowns has neither benefit nor harm compared to the use of reusable drapes and gowns (OR: 0.85; 95% CI: 0.66-1.09). In addition, the meta-analysis of the 2 observational studies showed a similar result (OR: 1.56; 95% CI: 0.89-2.72)]. (Appendix 4, comparison 1.1).

The quality of the evidence for this comparison was moderate for the RCTs and very low for the observational studies, both due to imprecision (Appendix 5).

1.2 One study<sup>17</sup> was identified comparing the use of disposable fenestrated drapes designed originally for cardiac catheterization with traditional draping that involved the use of multiple reusable cloth drapes. The study showed that the intervention may

have some effect to reduce SSI (OR: 0.07; 95% CI: 0.01-0.61) (Appendix 4, comparison 1.2).

There are limitations to this analysis. There are only a few studies available on this topic. In addition, studies used different SSI definitions and different types and material of drapes and gowns. In one study<sup>17</sup>, surgical procedures in the intervention group were performed by the senior experienced surgeons, while they were done by less experienced surgeons in the control group. In an observational study with a before/after design<sup>16</sup>, potential bias may have been introduced due to two study periods. In one study<sup>18</sup>, postoperative follow-up was for 10 days only.

2. No studies related to **PICO question 2** were identified (assessment of whether changing drapes during operations affects the risk of SSI).

### 3. Findings related to **PICO question 3**

Six studies (3 RCTs<sup>20,23,24</sup>, one quasi-RCT<sup>19</sup> and 2 observational studies<sup>21,22</sup>) comparing single-use disposable *adhesive incise drapes* (antimicrobial-impregnated or non-impregnated) to *non-adhesive incise drapes* for the reduction of the risk of SSI were identified.

After careful appraisal of the studies, the following **2 comparisons** were performed:

3.1 Adhesive antimicrobial-impregnated incise drapes vs. no drapes.

3.2 Adhesive non-impregnated incise drapes vs. no drapes.

#### *Results according to the comparisons*

3.1 Four studies (one RCT<sup>20</sup>, one quasi-RCT<sup>19</sup> and 2 observational studies<sup>21,22</sup>) were identified that assessed the effect of using single-use adhesive incise drapes to reduce SSI. Patients were adults undergoing elective clean and clean-contaminated surgical procedures (open appendectomy, cardiac, laparoscopic ventral and incisional hernia repair and liver resection for hepatocellular carcinoma). Three studies used the same iodine-impregnated antimicrobial film incise drape and one did not specify the type used.

The effect varied among the included studies. The 2 RCTs showed that the use of antimicrobial-impregnated incise drapes may have some harm, but the effect estimate was not statistically different from the control group. By contrast, the observational studies reported that there may be a benefit in using antimicrobial-impregnated incise drapes, but the effect was also not statistically different from the control group.

Meta-analysis of the 2 RCTs showed that the use of antimicrobial-impregnated incise drapes has neither benefit nor harm compared to no drapes in reducing SSI (OR: 2.62; 95% CI: 0.68-10.04). The meta-analysis of the 2 observational studies showed a similar result (OR: 0.49; 95% CI: 0.16 – 1.49) (Appendix 4, comparison 3.1).

The quality of evidence for these comparisons was very low for both the RCTs and the observational studies due to the risk of bias and imprecision or inconsistency (Appendix 5).

3.2 Two RCTs<sup>23,24</sup> evaluated the effect of using non-antimicrobial-impregnated adhesive incise drapes vs. no drapes to reduce SSI. Both studies used the same type and brand of non-impregnated adhesive incise drapes. Patients were adults undergoing fixation of hip fractures in one study and caesarean section in the other. No observational studies were identified for this comparison. Despite the difference in patient population and surgical procedures, the effect estimate reported was similar in both studies.

Meta-analysis of the 2 RCTs showed that the use of non-antimicrobial-impregnated incise drapes has neither benefit nor harm compared to no drapes in reducing SSI (OR: 1.10; 95% CI: 0.68 – 1.78) (Appendix 4, comparison 3.2).

The quality of evidence for this comparison was low due to imprecision (Appendix 5).

There is a limitation to this analysis as the number of studies is small with small sample sizes and different surgical procedures. A methodological risk of bias was identified in the design of the included studies, including variations in the definition of SSI and the duration of patient follow-up postoperatively.

In conclusion, an overall very low (RCTs and observational studies) quality of evidence shows that the use of disposable single-use drapes and gowns is neither beneficial nor harmful in reducing the SSI rate when compared to reusable drapes and gowns. No evidence was retrieved to evaluate the effect of an intraoperative change of drapes on the SSI rate. Again, an overall very low (RCTs and observational studies) quality of evidence shows that the use of antimicrobial-impregnated incise drapes has neither benefit nor harm compared to no drapes in reducing SSI. An overall low (2 RCTs) quality of evidence shows that the use of non-antimicrobial-impregnated incise drapes has neither benefit nor harm compared to no drapes in reducing SSI.

## **6. Other factors considered in the review of studies**

The systematic review team identified the following other factors to be considered.

### *Potential harms*

Adhesive bands of single-use drapes are reported to have a potential to provoke skin rash or eczema<sup>16</sup>. Allergic reactions are possible adverse events, for example, allergic contact dermatitis associated with the use of iodophor-impregnated drapes<sup>25</sup>.

### *Resource use*

There are many different aspects that need to be taken into account when evaluating the resource implications for the use of disposable vs. reusable drapes and surgical gowns. These include, but are not limited to, direct purchase costs and costs related to laundry and sterilization, labour and waste disposal<sup>26</sup>. Two studies<sup>27,28</sup> showed lower costs associated with the use of disposable drapes and gowns, whereas a cost-benefit analysis<sup>26</sup> found costs to be relatively higher for disposable drapes and gowns compared with reusable ones. Other authors reported that costs were similar for disposable and reusable items<sup>29,30</sup>. The heterogeneous findings of the available data on resource implications suggest that disposable and reusable surgical drapes and gowns are probably similar in costs.

Limited availability and costs may represent a burden in low- and middle-income countries (LMICs), whereas labour costs may be less of an issue compared to high-income countries. The disposal of single-use drapes and gowns and the ecological impact should be considered as their use generates additional clinical waste. Finally, the availability of adhesive incise drapes in LMICs may be limited and the purchase represents a high financial burden. Considering the lack of evidence for any benefit for the prevention of SSI, the additional cost for plastic adhesive incise drapes is not justified, irrespective of the setting.

## **7. Key uncertainties and future research priorities**

The available evidence is limited and comes mainly from high-income countries. More well-designed RCTs investigating the use of disposable drapes and surgical gowns compared to reusable drapes and surgical gowns in terms of SSI prevention are needed, especially in LMICs. One of the main research priority areas is to investigate whether drapes should be changed during the operation and if this measure has an effect on SSI rates. Further research should focus also on different types of materials (including permeable and impermeable materials) and address environmental concerns (water, energy, laundry, waste, etc.). Cost-effectiveness analyses of disposable compared to reusable drapes and gowns are very welcome, particularly in LMICs. The use of adhesive incise drapes is not considered a high priority topic in the field of SSI prevention research. Nevertheless, well-designed RCTs are encouraged to further investigate the potential benefits of these products, which are aggressively promoted by the manufacturing companies.

## APPENDICES

### Appendix 1: Search terms

#### *Drapes*

##### Medline (through PubMed):

- 1 "surgical wound infection"[Mesh] OR surgical site infection\* [TIAB] OR "SSI" OR "SSIs" OR surgical wound infection\* [TIAB] OR surgical infection\*[TIAB] OR post-operative wound infection\* [TIAB] OR postoperative wound infection\* [TIAB] OR wound infection\*[TIAB]
- 2 "surgical drapes"[Mesh] OR "surgical attire"[Mesh] OR "protective clothing"[Mesh]OR "disposable equipment"[Mesh] OR "equipment reuse"[Mesh] OR drape\* [TIAB] OR gown\* [TIAB] OR steridrape\*[TIAB] OR opsite\* [TIAB] OR ioban\*[TIAB]
- 3 Step 1 AND Step 2
- 4 "colony count, microbial"[Mesh] or colonization [TIAB] OR transmission [TIAB] OR contamination [TIAB]
- 5 "surgical drapes"[Mesh] OR "surgical attire"[Mesh]
- 6 Step 4 AND Step 5
- 7 Step 3 OR Step 6
- 8 AND ("1990/01/01"[PDat] : "2014/12/31"[PDat] )

##### EMBASE

- 1 surgical infection/ or (surgical site infection\* or SSI or SSIs or surgical wound infection\* or surgical infection\* or post-operative wound infection\* or postoperative wound infection\*).ti,ab,kw.
- 2 exp disposable equipment/ or exp plastic/ or exp surgical equipment/ or exp surgical drape/ or drape.mp. or exp povidone iodine/ or exp protective clothing/ OR steridrape.mp. OR opsite.mp. or exp opsite/ OR ioban.mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]
- 3 Step 1 AND Step 2
- 4 surgery.ti,ab,kw
- 5 colony count, microbial.ti,ab,kw. OR colonization.ti,ab,kw. OR contamination.ti,ab,kw. OR transmission.ti,ab,kw.
- 6 Step 2 AND Step 4 AND Step 5
- 7 Step 3 OR Step 6
- 8 limit 7 to yr="1990 -Current"
- 9 limit 8 to exclude medline journals

## **CINAHL**

S3 S2 OR S1

S2 (MM "surgical draping") OR "drapes"

S1 (MH "wound infection+") OR "wound infection" OR (MH "surgical wound infection")

## **Cochrane CENTRAL**

1. wound infection:ti,ab,kw

2. surgical wound infection:ti,ab,kw

3. drapes

4. 1 or 2

5.4 AND 3

## **WHO regional medical databases**

1. (ssi)

2. (surgical site infection)

3. (surgical site infections)

4. (wound infection)

5. (wound infections)

6. (postoperative wound infection)

7. (surgical drapes)

8. (drapes)

## ***Surgical gowns***

### **Medline (through PubMed):**

See above (included in the search strategy for drapes).

## **EMBASE**

1 surgical infection/ or (surgical site infection\* or SSI or SSIs or surgical wound infection\* or surgical infection\* or post-operative wound infection\* or postoperative wound infection\*).ti,ab,kw.

2 exp clothing/ or surgical gown.mp. or exp protective clothing/ or exp surgical gown/ OR surgical attire.mp. or exp surgical attire/

3 Step 1 AND Step 2

4 surgery.ti,ab,kw

5 colony count, microbial.ti,ab,kw. OR colonization.ti,ab,kw. OR contamination.ti,ab,kw. OR transmission.ti,ab,kw.

6 Step 2 AND Step 4 AND Step 5

7 Step 3 OR Step 6

8 limit 7 to yr="1990 - current"

9 limit 8 to exclude Medline journals

## **CINAHL**

S5 S4 AND S1

S4 S3 and S2

S3 "surgical attire"

S2 "gown" OR (MH "dressing")

S1 (MH "wound infection+") OR "wound infection" OR (MH "surgical wound infection")

## **Cochrane CENTRAL**

1. wound infection:ti,ab,kw

2. surgical wound infection:ti,ab,kw

3. gown

4. surgical attire

5. 1 or 2

5. 4 AND 3

6. 5 or 6

## **WHO regional medical databases**

((SSI) OR (surgical site infection) OR (surgical site infections) OR (wound infection) OR (wound infections)) AND ((gowns) OR (gown) OR (surgical attire))

ti: title; ab: abstract; kw: keyword

## Appendix 2: Evidence tables

### Comparison 2.1: Single-use disposable drapes and/or surgical gowns vs. reusable drapes and/or surgical gowns

Author, year, reference	Type and duration of study/ setting	Intervention	Comparator	Primary outcome	Results	Other comments/limitations
Bellchambers, 1999 <sup>14</sup>	RCT 18 months (July 1995 - December 1996) Australia 505 coronary artery surgery patients Each patient followed up for 3 months Tertiary referral centre for cardiac surgery	Disposable paper drape system including an iodophor-impregnated adhesive plastic drape, which covered the central thorax and abdomen (no further specifications for this type of drape).  The operating surgeon, assistants and scrub nurses wore gowns of the same material as the drapes.	Reusable fabric drapes (not specified) including an iodophor-impregnated adhesive plastic drape covering the anterior thorax.  The operating surgeon, assistants and scrub nurses wore gowns of the same material as the drapes.	<b>SSI</b> using the wound scoring system ASEPSSIS (Additional treatment, the presence of Serous discharge, Erythema, Purulent discharge and Separation of the deep tissues, the Isolation of bacteria and the duration of inpatient Stay).  The total score used to reflect the severity of infection is as follows: 0–10 □□satisfactory healing 11–20 □□disturbance of healing 21–30 □□minor wound infection 31–40 □□moderate wound infection >41 □□severe wound infection.	Sternal wounds:  Intervention: 13/250  Comparator: 12/236  $P = 0.87$  Leg wounds:  Intervention: 27/234  Comparator: 31/216  $P = 0.78$	Allocation was stratified according to whether or not the patient had previous coronary artery surgery.  Patients were allocated using sealed envelopes containing a series of computer-generated random numbers.  Outcome assessor blinded.  15 patients died during the follow-up period of the study. No further comments on the cause of death.

Author, year, reference	Type and duration of study/ setting	Intervention	Comparator	Primary outcome	Results	Other comments/limitations
Belkin, 1998 <sup>15</sup>	<p>Quasi-RCT (2-week alternate cycle use of intervention and comparator), 5 months</p> <p>USA</p> <p>Class 1 clean and class 2 clean-contaminated</p> <p>General, cardiothoracic, orthopaedic, neuro-surgery, plastic and other surgery</p> <p>Each patient followed up 7 to 28 days</p> <p>Teaching hospital</p>	<p>Disposable, non-woven gowns and drapes (spun-laced material identified commercially as Sontara®, Jacob Holm Group, Basel, Switzerland)</p>	<p>Reusable fabric gowns and drapes (128-thread count fabric consisting of a blend of 65% polyester, 34% cotton, and 1% stainless steel. Sleeves and front of the gowns were made with two-ply.</p>	<p><b>Infected wound: defined as when pus is visible in wound (not matching with CDC definition).</b></p>	<p>Wound infection:</p> <p>Intervention: 108/2139</p> <p>Comparator: 133/2223</p> <p><i>P</i> =0.177</p>	<p>Excluded from the study:</p> <ul style="list-style-type: none"> <li>- classes 3 and 4: contaminated or dirty</li> <li>- ophthalmology</li> <li>- no visible wound</li> <li>- any procedure performed outside the operating room</li> <li>- if no primary closure</li> </ul> <p>Outcome assessor blinded</p>

Author, year, reference	Type and duration of study/ setting	Intervention	Comparator	Primary outcome	Results	Other comments/limitations
Castro Ferrer, 2004 <sup>16</sup>  [Full text in Spanish]	Observational, single non-teaching centre One year of observation (before intervention and after intervention); 6 months of training (wash-in phase) – single-use drapes  Spain  Type of procedures: general surgery	Single-use adhesive surgical drapes (the adhesive concept applies to how the drape is secured to the surrounding area of the surgical field).  The intervention also included non-reusable gowns (Klinidrape, Molnlycke Health Care).	Conventional reusable drapes and gowns	Wound infection rate (incisional SSI)	Wound infection Single-use: 31/421 (7.4%) Reusable drapes 18/396 (4.5%) Stratified by type of surgical contamination: Clean: I: 8/204 (3.9%) C: 2/167 (1.29%) Clean-contaminated I: 5/96 (5.2%) C: 3/100 (3%) Contaminated-dirty I: 11/76 (14.5%) C: 8/83 (9.6%) Dirty I: 7/45 (15.6%) C: 5/46 (10.8%)	– Additional outcomes were also analyzed, such as staff satisfaction. – Analysis of the different properties of the new material was done, that is: – impermeability – isolation – liquid absorption – resistance.  Potential bias may have been introduced due to different patient populations in the 2 study periods. Nevertheless, the type of surgery regarding the degree of contamination seems equipoise between both periods. No data on additional risk factors that may have influenced SSI, such as the ASA score, are reported. No data on the degree of wound infection.  – No data about blinding assessment of SSI is reported or participant blinding. – Interestingly, adverse effects of adhesive drapes are taken into consideration (9% of skin rash or eczema).

Author, year, reference	Type and duration of study/ setting	Intervention	Comparator	Primary outcome	Results	Other comments/limitations
Gallagher, 2007 <sup>17</sup>	Prospective non-randomized study, 3 years  Italy  364 pacemaker and implantable cardioverter defibrillator patients	Simplified draping method: disposable single adhesive fenestrated drape designed originally for use in cardiac catheterization.	Traditional draping: involves the use of multiple cloth drapes; adhesive strips and draping clamps are used to maintain the position of drapes.	Suspected and confirmed infection  Definition not provided	Intervention: 1/250  Comparator: 6/114  <i>P</i> =0.014	Intervention procedures performed by the same experienced operator (first operator experience >500 pacing procedures before the current series); control procedures performed by 3 other operators in the same catheterization laboratory over the same period. These operators were less experienced, each having first operator experience of <100 cases at the start of the study period.  – Cephalic access was used for 71% of ventricular leads and 60% of atrial leads; in both cases significantly lower proportions than in the study group ( <i>P</i> = 0.001) – Poor comparability between intervention and comparator.
Treggiari, 1992 <sup>18</sup>  [Full text in Italian]	Prospective, non-randomized, non-controlled study  Italy	Disposable non-woven fabric drapes and gowns (TNT fabric 450).	Conventional reusable cotton drapes and gowns.	Wound infection (named as “postoperative infection”)	Wound infection:  Non-woven fabric drapes: 4/25  Conventional cotton drapes: 4/25  Non-significant	– SSI definitions not reported – Surveillance only until postoperative day 10.

SSI: surgical site infection; RCT: randomized controlled trial; CDC: Centers for Disease Control and Prevention; I: Intervention; C: Comparator.

**Comparison 3: Single use disposable adhesive incise drape (antimicrobial or non-impregnated) vs. no adhesive incise drapes**

Author, year, reference	Type & duration of study/ Setting	Intervention	Comparator	Primary outcome	Results	Other comments/limitations
Al Qahtani 2014 <sup>19</sup>	<p>Quasi-RCT</p> <p>January-December 2012</p> <p>Saudi Arabia</p> <p>91 patients &gt;12 years of age presenting to the emergency department with signs of acute appendicitis</p> <p>Open appendectomy</p> <p>Each patient followed up for 6 weeks</p> <p>Tertiary care hospital</p>	<p>Standard 5-minute skin preparation with 10% povidone-iodine soap followed by the application of an antimicrobial film incise drape (Loban_2 incise drapes; 3M, St Paul, MN, USA)</p>	<p>Standard skin preparation alone</p> <p>No description of conventional draping in this group.</p>	<p>Superficial SSI infection using the CDC definition</p>	<p>Intervention: 6/52</p> <p>Comparator: 2/39</p> <p>Relative risk: 2.2 (95% CI: 0.50–10.5).</p> <p>(<i>P</i>=0.459)</p>	<ul style="list-style-type: none"> <li>– Patient assignment done initially on an alternating-day schedule, then on a weekly basis.</li> <li>– Excluded cases done laparoscopically or by a different surgical team.</li> <li>– Excluded cases in which the research criteria were breached, such as the use of a different antibiotic regimen or incision closure in a different way.</li> <li>– 4 (50%) of the 8 patients with a postoperative SSI had pelvic drain insertion, whereas only</li> <li>– 11 (13%) of the 83 patients without SSI had pelvic drain insertion (<i>P</i>=0.007).</li> <li>– Incise drapes were easy to use and there were no reported sensitivity reactions.</li> <li>– Of the 6 patients in the antimicrobial film group with postoperative SSI, 3 had a perforated appendix, 2 had a gangrenous appendix and one had an inflamed appendix.</li> <li>– In group 2, one patient had an inflamed appendix and the other had a perforated appendix.</li> </ul>

Author, year, reference	Type & duration of study/ Setting	Intervention	Comparator	Primary outcome	Results	Other comments/limitations
Segal, 2002 <sup>20</sup>	RCT USA 184 high risk cardiac patients Each patient followed up for 6 weeks 900-bed tertiary hospital	Group 4: one-step iodophor/alcohol water insoluble film with iodine-impregnated incise drape.	Group 3: one-step iodophore/alcohol water insoluble film.  This study had 2 more arms:  group 1: povidone-iodine soluble paint.  group 2: povidone-iodine 5-minute soluble scrub with paint.	Sternal SSI (according to the CDC definition)	Intervention (group 4): 3/51  Comparator (group 3): 1/50	<ul style="list-style-type: none"> <li>- The study primary objective was to compare preoperative skin preparations.</li> <li>- Only high risk patients were included.</li> <li>- Outcome assessor blinding is not clear.</li> <li>- Secondary analysis of soluble vs. insoluble iodine is significant, <math>P=0.02</math>.</li> <li>- Demographics: matching/differences between groups not provided.</li> </ul>

Author, year, reference	Type & duration of study/ Setting	Intervention	Comparator	Primary outcome	Results	Other comments/limitations
Swenson, 2008 <sup>21</sup>	Observational retrospective cohort study  1 March 1 2002 to 30 June 30 2006  USA  Clean, elective, laparoscopic ventral and incisional hernia repair with mesh implementation.  Department of surgery, university hospital	Group 1: use of antimicrobial incise drape impregnated with iodophore containing adhesive compound (Loban™, 3M)	Group 2:  No antimicrobial-impregnated adhesive drape.	<b>SSI</b> was defined as all mesh infections in the first 30-day postoperative period, as well as SSI not related to the mesh.  <b>Mesh infection</b> was defined as infection that necessitated the operative removal of the mesh.	<b>SSI:</b> <b>drape group: 25/206</b>  <b>non-drape group: 45/300</b>  <i>P</i> =0.36  Mesh infection:  <b>drape group: 16/206</b>  <b>non-drape group: 26/300</b>  <i>P</i> =0.72	- Antimicrobial-impregnated drapes were used more: - in laparoscopic procedures - by residents - by high volume surgeons - for urgent or emergency repair  Clean wound classification Current or recent smoking habit Haemodialysis patients Chronic steroid use Peripheral vascular disease

Author, year, reference	Type & duration of study/ Setting	Intervention	Comparator	Primary outcome	Results	Other comments/limitations
Yoshimura, 2003 <sup>22</sup>	<p><b>Retrospective study</b></p> <p>April 1994 to end December 2001</p> <p>Japan</p> <p>Age range: 29 to 80 years</p> <p>Follow-up: 30 days</p> <p><b>Clean-contaminated liver resection for hepatocellular carcinoma</b></p> <p><b>University hospital</b></p>	<p><b>Plastic adhesive incise drape impregnated with an iodophor</b></p> <p>(Loban™ 2 incise drapes; 3M)</p>	No antimicrobial-impregnated incise adhesive drape	Wound infection (purulent drainage from the superficial incision with or without laboratory confirmation plus one or more of the following signs was required: pain or tenderness, localized swelling or redness or heat)	<p>Wound infection:</p> <p>Impregnated drape: 4/122</p> <p>No drape: 21/174</p> <p><math>P= 0.0096</math></p>	<ul style="list-style-type: none"> <li>- There were significant differences between the groups in terms of gender, the indocyanine retention test at 15 minutes, aspartate aminotransferase and alanine aminotransferase levels, duration of the preoperative hospital stay, intraoperative blood loss, and the percentage of autologous blood transfusion.</li> <li>- By multivariate regression analysis, body mass index, smoking and lack of drape use were independent risk factors for wound infection.</li> <li>- Most of the bacteria isolated were skin bacteria, including <i>Staphylococcus aureus</i> and <i>S. epidermidis</i>.</li> <li>- Patients who had had a simultaneous operation for other cancers, including carcinoma of the gastrointestinal tract, were excluded.</li> <li>- Wound infections associated with intra-abdominal infections were omitted because an intra-abdominal infection might cause a wound infection.</li> </ul>

Author, year, reference	Type and duration of study/ Setting	Intervention	Comparator	Primary outcome	Results	Other comments/limitations
Chiu, 1993 <sup>23</sup>	RCT January – December 1991 Hong Kong (SAR, China) Follow-up: 6 months Age range: 43-97 years Fixation of hip fractures University hospital	Cover the operation site with plastic adhesive incise drape (Opsite™, Smith & Nephew, London, UK; not antimicrobial-impregnated).	Operation site left uncovered “no drape”-	<b>Wound infection</b> <b>Positive swab at wound closures</b>	<b>Wound infection:</b> Intervention: 6/65 Comparator: 5/55 <i>P</i> = 0.90 <b>Positive swab at wound closures:</b> Intervention: 4/65 Comparator: 1/55 <i>P</i> = 0.25	<ul style="list-style-type: none"> <li>- In both groups the operation site was prepared with povidone solution and draped with sterile towels.</li> <li>- None of the skin swabs taken before incision grew bacteria.</li> <li>- In the drape group, 2/6 of patients with wound infection had positive swabs.</li> <li>- Positive swab at wound closure in the no-drape group was not associated with wound infection.</li> </ul>

Author, year, reference	Type and duration of study/ Setting	Intervention	Comparator	Primary outcome	Results	Other comments/limitations
Ward, 2001 <sup>24</sup>	RCT, double-blind  18 August 1992 – 29 January 1993  South Africa  Caesarean section  Regional referral university hospital	Plastic adhesive (not impregnated) incise drapes.  (Opsite™, Smith & Nephew; not antimicrobial-impregnated).	No plastic adhesive incise drapes	Wound infection: infection was diagnosed if 2 of 3 features were present: - erythematous cellulitis (erythematous induration either side of the incision line) - seropurulent discharge from the wound - positive swab culture (organisms and leucocytes)  Secondary outcome: postoperative length of stay	Wound infection  Intervention group: 34/305  Control group: 30/298  <i>P</i> = 0.6933	– 8 patients were excluded from randomization due to clinically suspected ruptured uterus. – 2 women from the control group were subsequently excluded, one having a coincidental appendix rupture discovered at caesarean section and the other requesting early discharge on day 2 after caesarean section wound. – Standard sterile double-towel draping applied for all cases. – Sepsis developing after 5 days was not included.

SSI: surgical site infection; RCT: randomized controlled trial; CDC: Centers for Disease Control and Prevention; ASA: American Society of Anesthesiologists

**Appendix 3a: Risk of bias assessment of the included studies – RCTs and quasi-RCTs**

Author, year, reference	Sequence generation	Allocation concealment	Participants and personnel blinded	Outcome assessors blinded	Incomplete outcome data	Selective outcome reporting	Other sources of bias
Al Qahtani* 2014 <sup>19</sup>	High	High	High	High	low	Low	Unclear
Belkin* 1998 <sup>15</sup>	High	High	High	Low	Low	Low	Low
Bellchambers 1999 <sup>14</sup>	Low	Low	High	Low	Low	Low	Low
Chiu 1993 <sup>23</sup>	Unclear	Unclear	High	Unclear	Low	Low	Low
Segal 2002 <sup>20</sup>	Low	Low	High	High	Low	Low	Low
Ward 2001 <sup>24</sup>	Low	Low	High	Low	Low	Low	Unclear

\*quasi-randomized; RCT: randomized controlled trial.

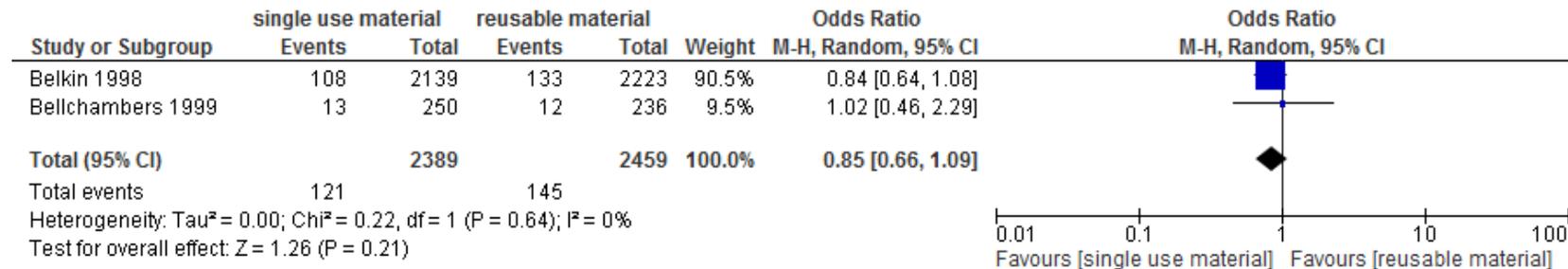
**Appendix 3b: Risk of bias assessment of the included non-randomized studies**

<i>Cohort studies</i> Author, year, reference	Representative- ness of cohort	Selection of non-exposed cohort	Ascertainment of exposure	Demonstration that outcome of interest was not present at start	Comparability of cohorts	Assessment of outcome	Follow-up long enough	Adequacy of follow-up of cohorts
Castro Ferrer 2004 <sup>16</sup>	B(*)	A(*)	A(*)	A(*)	AB(**)	B(*)	A(*)	B(*)
Gallagher 2007 <sup>17</sup>	B(*)	A(*)	A(*)	A(*)	-	B(*)	A(*)	-
Swenson 2008 <sup>21</sup>	B(*)	A(*)	A(*)	A(*)	A(*)	B(*)	A(*)	B(*)
Treggiari 1992 <sup>18</sup>	B(*)	A(*)	A(*)	A(*)	A(*)	B(*)	-	-
Yoshimura 2003 <sup>22</sup>	B(*)	A(*)	A(*)	A(*)	AB(**)	A(*)	A(*)	A(*)

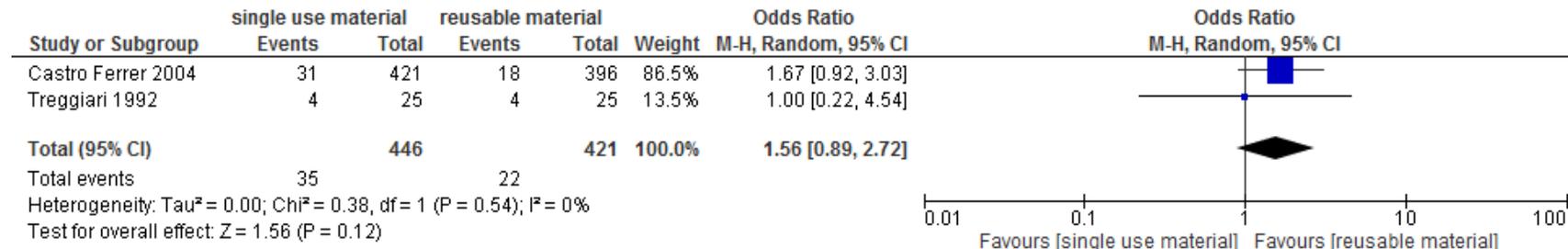
## Appendix 4: Comparisons:

### Q1: Single use, disposable drapes and surgical gowns vs. reusable drapes and surgical gowns

Forest plot of comparison: 1 RCT, 1 quasi-RCT



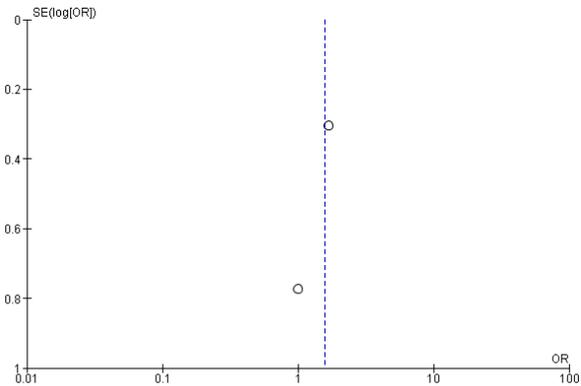
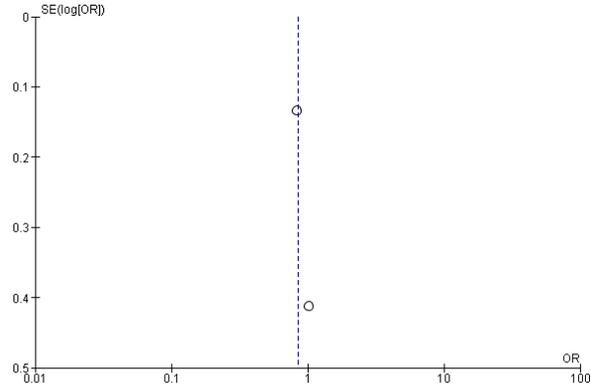
Forest plot of comparison: Observational studies



RCT: randomized controlled trial; M-H: Mantel-Haenszel (**test**); CI: confidence interval

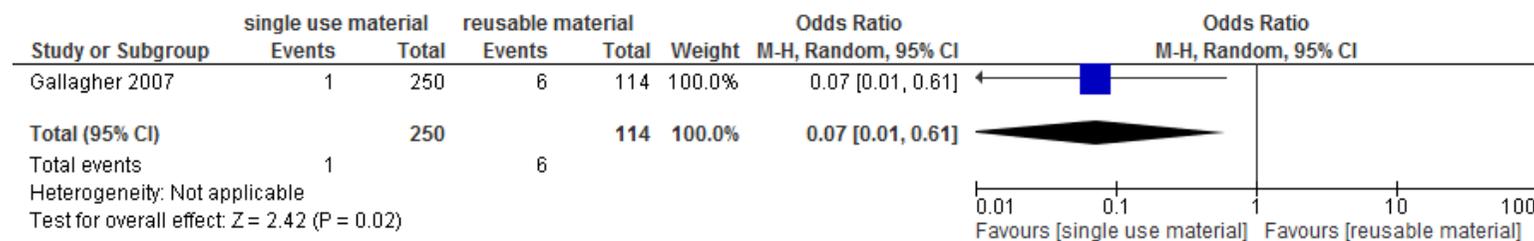
Funnel plots Q1: Single-use disposable drapes and surgical gowns vs. reusable drapes and surgical gowns

(RCTs, left; observational studies, right)



### Q1.1: Single-use disposable drapes vs. reusable drapes only

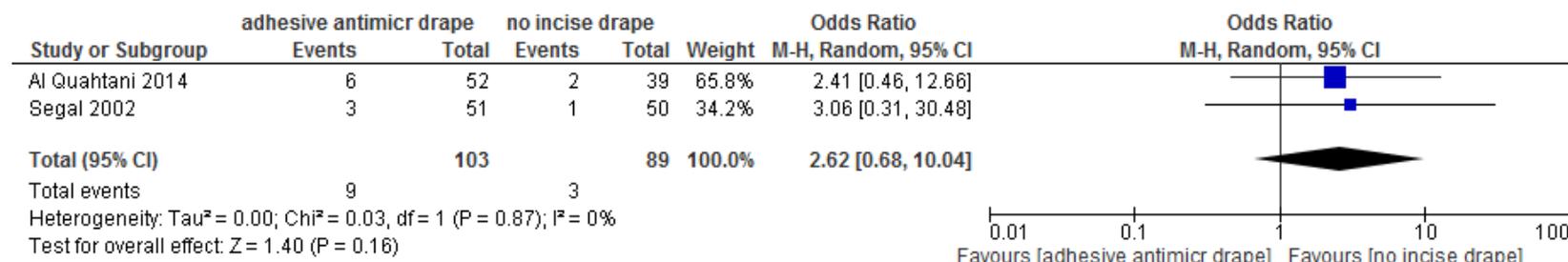
Forest plot of comparison: 1 observational study



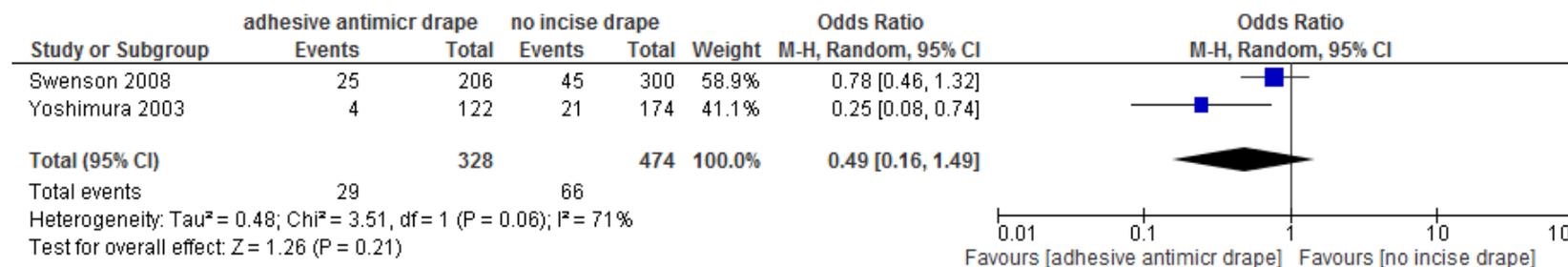
RCT: randomized controlled trial; M-H: Mantel-Haenszel (test); CI: confidence interval

### Q3: Single-use disposable adhesive incise drape (antimicrobial or non-impregnated) vs. no adhesive incise drapes

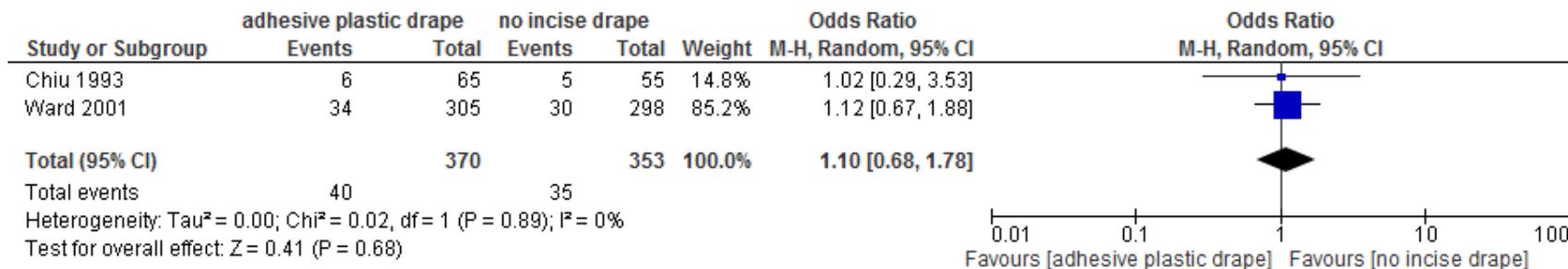
Forest plot of comparison: 1 RCT, 1 quasi-RCT – *iodine-impregnated drape*



Forest plot of comparison: Observational studies – *iodine-impregnated drape*

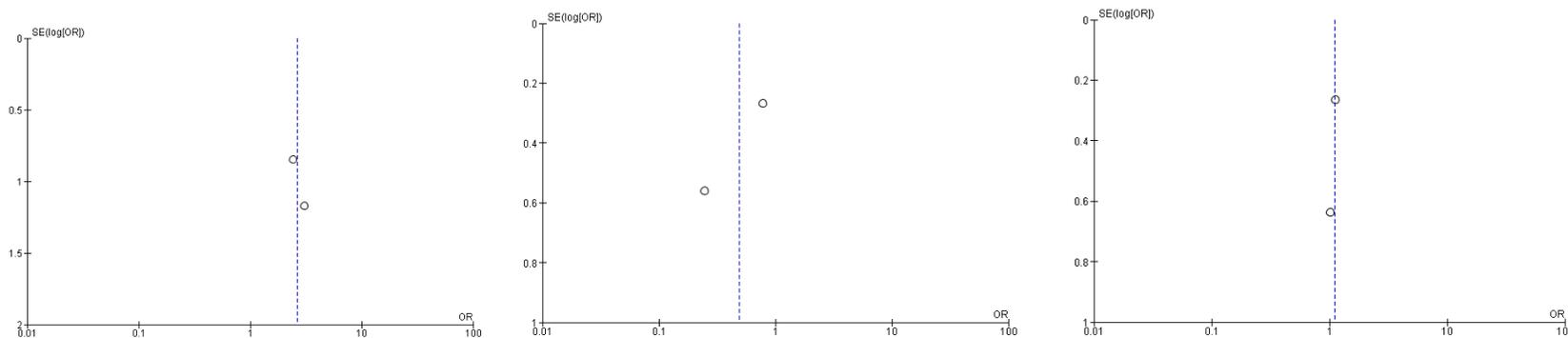


Forest plot of comparison: RCTs – *non-impregnated drape*



Funnel plots Q3: **Single-use disposable adhesive incise drape (antimicrobial or non-impregnated) vs. no adhesive incise drapes**

(*iodine-impregnated*: RCTs trials [left], observational studies [middle]; *non-impregnated*: RCTs [right])



RCT: randomized controlled trial; M-H: Mantel-Haenszel (test); CI: confidence interval

## Appendix 5: GRADE tables

### Q1: Single-use, disposable drapes and/or surgical gowns vs. reusable drapes and/or surgical gowns

Quality assessment							№ of patients		Effect		Quality
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Single-use drapes and gowns	Reusable drapes and gowns	Relative (95% CI)	Absolute (95% CI)	
Surgical site infection (drapes and gowns)											
2	RCTs	not serious	not serious	not serious	serious <sup>1</sup>	none	121/2389 (5.1%)	145/2459 (5.9%)	<b>OR: 0.85</b> (0.66-1.09)	<b>8 fewer per 1000</b> (from 5 more to 19 fewer)	⊕⊕⊕○ MODERATE
Surgical site infection (drapes and gowns)											
2	Observational studies	not serious	not serious	not serious	serious <sup>2</sup>	none	35/446 (7.8%)	22/421 (5.2%)	<b>OR: 1.56</b> (0.89-2.72)	<b>27 more per 1000</b> (from 5 fewer to 78 more)	⊕○○○ VERY LOW
Surgical site infection (drapes only)											
1	Observational studies	serious <sup>3</sup>	not serious	serious <sup>4</sup>	very serious <sup>5</sup>	none	1/250 (0.4%)	6/114 (5.3%)	<b>OR: 0.07</b> (0.01-0.61)	<b>49 fewer per 1000</b> (from 20 fewer to 52 fewer)	⊕○○○ VERY LOW

1. Optimal information size met but CI overlaps no effect and fails to exclude important benefit or important harm (RR or RRR of 25%)
2. Optimal information size not met
3. Risk of selection bias, performance bias and detection bias
4. Only pacemaker and implantable cardioverter defibrillator procedures
5. Optimal information size not met and CI fails to exclude both appreciable benefit and harm (RR and RRR of 25%)

RCT: randomized controlled trials; SSI: surgical site infection; CI: confidence interval. OR: odds ratio; RR: relative risk; RRR: relative risk reduction

### Q3: Single-use disposable adhesive incise drape (antimicrobial or non-impregnated) vs. no adhesive incise drapes

Quality assessment							№ of patients		Effect		Quality
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Adhesive incise drapes	No incise drapes	Relative (95% CI)	Absolute (95% CI)	
Surgical site infection (iodine-impregnated drapes)											
2	RCTs	serious <sup>1</sup>	not serious	not serious	very serious <sup>2</sup>	none	9/103 (8.7%)	3/89 (3.4%)	<b>OR: 2.62</b> (0.68-10.04)	<b>50 more per 1000</b> (from 11 fewer to 226 more)	⊕○○○ VERY LOW
Surgical site infection (iodine-impregnated drapes )											
2	Observational studies	not serious	serious <sup>3</sup>	not serious	very serious <sup>2</sup>	none	29/328 (8.8%)	66/474 (13.9%)	<b>OR: 0.49</b> (0.16-1.49)	<b>66 fewer per 1000</b> (from 55 more to 114 fewer)	⊕○○○ VERY LOW
Surgical site infection (non-impregnated drapes)											
2	RCTs	not serious	not serious	not serious	very serious <sup>2</sup>	none	40/370 (10.8%)	35/353 (9.9%)	<b>OR: 1.10</b> (0.68-1.78)	<b>9 more per 1000</b> (from 30 fewer to 65 more)	⊕⊕○○ LOW

1. Risk of detection bias
2. Optimal information size not met and CI fails to exclude both appreciable benefit and harm (RR and RRR of 25%)
3. High heterogeneity, I<sup>2</sup>=71%

RCT: randomized controlled trial; SSI: surgical site infection; CI: confidence interval. OR: odds ratio; RR: relative risk; RRR: relative risk reduction

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